Inventors:

Serial No.: Filing Date:

DEX-0207

Macina et al. 09/867,034

May 29, 2001

Page 3

nonelected species. Thus, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 1 to recite the elected species SEQ ID NO: 5. However, in accordance with the finality of the Restriction Requirement, Applicants reserve the right to file divisional and or continuation application(s) to the canceled subject matter.

I. Objection to Claim 15

The Examiner objected to Claim 15 as being dependent upon a rejected base claim. The Examiner has acknowledged that claim 15 would be allowable if rewritten in independent form including all the limitations of the base claim.

Applicants have followed the Examiners suggestion and claim 15 has been rewritten in independent form. Accordingly, withdrawal of the objection to claim 15 is respectfully requested.

II. Rejection of Claims under 35 U.S.C. 112, first paragraph

Claim 1 remains rejected under 35 U.S.C. 112, first paragraph, for lack of enablement. The Examiner has acknowledged the specification to be enabling for SEQ ID NO: 5. However, the Examiner suggests that a sequence with 95% identity to SEQ ID NO: 5 is interpreted as being drawn to

Inventors:

Serial No.: Filing Date:

DEX-0207

Macina et al. 09/867,034

LAW OFFICES

May 29, 2001

Page 4

SEQ ID NO: 5 and it's allelic variants. The Examiner suggests that it is highly unpredictable if any allelic variant of SEQ ID NO: 5 could be used as a colon cancer marker and causes undue experimentation to practice the full scope of the claims. In support of this suggestion, the Examiner has cited Sasaki et al., a reference which discloses that a single nucleotide change may contribute to cancer development.

Applicants respectfully traverse this rejection.

The present invention relates to nucleic acid sequences over expressed in colon cancer. In contrast, the primary focus of Sasaki et al. is the role of polymorphisms of a single gene in disease incidences of endometrial cancer. Sasaki et al. acknowledge in the discussion that "the expression of ER α has been associated with estrogen-related tumors including endometrial cancer." Sasaki at 561. This over expression is clearly a separate issue from their efforts to identify inherited variants related to endometrial carcinogenesis. Accordingly, the reference relating to polymorphisms of estrogen receptor α gene hypothesized as being involved in endometrial cancer has little relevance to the instant invention of nucleic acid

Attorney Docket No.: DEX-0207

Inventors: Serial No.:

Filing Date:

Page 5

Macina et al.

LAW OFFICES

09/867,034 May 29, 2001

sequences over expressed in colon cancer.

Further, it is well known in that art that various cancers have different molecular modes of development and progression. For example, Ye et al. (Teratog Carcinog Mutagen 2002, 22(5):385-92; see abstract), a copy of which is provided herewith, have shown that genetic variation or polymorphisms of a gene does not necessarily vary the risk of cancer development. Ye et al. studied three enzymes associated with detoxification of carcinogens to determine an association between polymorphisms and colon cancer. The three enzymes studied were CYPIAI, GSTM1 and GSTT1 as the literature on polymorphisms and these enzymes and the human cancer risk was inconsistent. Ye et al. at 386. Ye et al. found no significant association between polymorphisms of these enzymes and colon cancer. Ye et al. a 390. polymorphism in a gene that contributes to development of endometrial cancer as taught by Sasaki et al. is not evidence that a polymorphism in a different gene is relevant to colon cancer.

Accordingly, the teachings of Sasaki et al. provide no reasonable basis to question the enablement of applicants' invention relating to over expressed colon cancer markers

Attorney Docket No.: DEX-0207

Inventors: Serial No.: Filing Date: Macina et al. 09/867,034 May 29, 2001

Page 6

confirmed by applicants' extensive experiments. The references discussed above show that there is no clear correlation between specific polymorphisms and cancer.

Moreover, Sasaki et al. relates to endometrial cancer, not colon cancer. Thus, withdrawal of this rejection is respectfully requested.

Claim 1 also remains rejected under 35 U.S.C. 112, first paragraph, as the Examiner suggests that claim 1 contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention. Specifically, the Examiner suggests that the definition of CSG indicates that claim 1 is drawn to SEQ ID NO: 5 and allelic variants that have 95% identity to SEQ ID NO: 5.

Applicants respectfully traverse this rejection.

It is respectfully pointed out that claim 1 has been amended to remove the term CSG from the preamble. The term CSG has been replaced with "an isolated and purified nucleic acid". Support for this amendment can be found at page 7 lines 21-31 and page 21 lines 7-9. Accordingly, the Examiner's comments relating to the definition of CSG in

Inventors: Serial No.: Filing Date: DEX-0207 Macina et al. 09/867,034 May 29, 2001

Page 7

relation to Claim 1 are no longer relevant.

In addition, without conceding correctness of the Examiner's position, applications have amended Claim 1 to recite 97% identity to SEQ ID NO: 5.

In accordance with MPEP 2163, an adequate written description of the invention may be shown by any description of sufficient, relevant and identifying characteristics so long as a person skilled in the art would recognize that the inventor has possession of the claimed invention. instant application, there is an explicit teaching of the characteristic of 97% identity to SEQ ID NO: 5 and the capability of hybridizing under stringent conditions to a antisense sequence of SEQ ID NO: 5. Specifically, at page 17, lines 34 though page 18, line 3, it is taught that polynucleolides of 97% identity are a preferred embodiment and at page 18 lines 10-17, the definition of stringent conditions for hybridization are taught. Further information regarding such sequences is not required since identifying polynucleotides sharing 97% identity with a disclosed sequence are well known in the art and need not be described in detail in the specification. See e.g. MPEP 2163 and Hybriditech, Inc. v. Monoclonal Antibodies, Inc.

Inventors:

Serial No.: Filing Date:

Page 8

DEX-0207

Macina et al. 09/867,034

May 29, 2001

802 F.2d 1367, 1379-80, 231 USPQ 81, 90 (Fed. Cir. 1986).

Accordingly, withdrawal of the rejection under 35 U.S.C. 112, first paragraph, for written description is respectfully requested.

VII. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record.

Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with Markings to Show Changes Made."

Respectfully submitted,

Kathleen A. Tyrrell

Registration No. 38,350

Date: March 6, 2003

Licata & Tyrrell P.C. 66 E. Main Street

Marlton, New Jersey 08053

(856) 810-1515

Inventors:
Serial No.:
Filing Date:

DEX-0207 Macina et al. 09/867,034 May 29, 2001

Page 9

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Please amend the claims as follows:

- 1. (Amended) An isolated and purified nucleic acid A CSG comprising:
 - (a) a polynucleotide of SEQ ID NO: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, or 22 or
 - (b) a polynucleotide with 9597% identity to SEQ ID NO: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, or 22 which is capable of hybridizing under stringent conditions to the antisense sequence of SEQ ID NO: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21 or 22.
- 15. (Amended) An isolated and purified nucleic acid

 The CSG of claim 1 wherein comprising the polynucleotide of

 comprises SEQ ID NO: 5.